IDENTIFYING CASES

1) Identify all patients (including deceased patients) who enrolled in the selected trial at your institution between October 1, 1998, and December 31, 1999.

IDENTIFYING CONTROLS VIA CANCER REGISTRY OR OTHER DATABASES (PROTOCOLS THAT INCLUDE NEWLY DIAGNOSED PATIENTS):

1) Definition—

   A “control” for this study is a patient meeting the eligibility criteria for one of the selected trials but who is not participating in that trial or any other clinical trial.

2) General Instructions—

   For the trials we are studying, including trials on which you have enrolled cases (patients enrolled in the selected clinical trial) as well as all other trials in CCTS, we need to identify all controls who have received care at your institution since October 1, 1998.

3) RAND will help you work with the cancer registry (or other databases) at your institution to create a list of patients who may be potential controls. RAND will contact you to coordinate this activity.
4) Once a list of potential controls has been created, please review the medical record for each potential control using the abridged list of protocol entry criteria (provided by RAND) for the trial to which the control is being matched.

5) Please keep RAND updated on the number of potential controls you have identified, and of the steps you have taken to identify controls, using the *Log for Control Patients* (provided by RAND).

**IDENTIFYING CONTROLS (PROTOCOLS THAT INCLUDE PATIENTS WITH PROGRESSED/RELAPSED CANCER)**

If your institution has enrolled cases in a protocol that includes progressed or relapsed (“nonanalytic”) patients, please take the following additional steps:

1) Please review the abridged list of protocol entry criteria for each of these trials (provided by RAND).

2) For each case enrolled in these trials at your institution, please identify at least one patient who received care at your institution from October 1, 1998, through December 31, 1999, who
   • met the abridged protocol entry criteria for that trial at any time between October 1, 1998, and December 31, 1999
   • did not enroll in that trial, for whatever reason
   • has not participated in any clinical trial since October 1, 1998, to the best of your knowledge.

3) Where to look for potential controls:
   • Review the list of patients who were offered participation in the trial but who turned it down (if available);
   • Consult with the Principal Investigator for the selected trial(s) and his or her colleagues to see if he or she can remember any patients who may have been eligible for the trial but who were not offered the trial or who turned the trial down (for whatever reason); please review these patients’ medical records to verify that they meet the protocol entry criteria for the selected trial.
• Periodically review the Principal Investigators’ general patient lists to see if there are any patients who look eligible but who were not asked to participate in the trial (for whatever reason); please review these patients’ medical records to verify that they meet the protocol entry criteria for the selected trial.

• Scan medical records to identify potential controls.

4) Please keep RAND updated on the number of potential controls you have identified, and of the steps you have taken to identify controls, using the Log for Control Patients (provided by RAND).

CONTACTING CASES AND CONTROLS

1) For each case (patient enrolled in a selected trial), and each control identified using the steps above, send the patient a letter requesting permission to release their name, contact information, and basic background information to RAND.

• Print the patient contact letter provided by RAND on your own institutional letterhead and ask the patient’s treating oncologist to sign the letter.

• Record the patient’s identification number, the date the letter was sent, and the enrollment status for that patient (agreed, refused, or pending) on the Patient Enrollment Log (provided by RAND). Please update and mail or fax this form to RAND every Friday.

• Record the patient’s name and telephone number(s) on the Call Record Sheet (provided by RAND) and record the outcome of every call you make to the patient on the call record. (Use this form to update the Patient Enrollment Log.)

2) Following up with Patients and Obtaining Consent

You must follow up with the patient by phone or in person to obtain verbal consent to release their name, contact information, and background information to RAND.

Ideally, phone follow-up with patients should take place no later than one week after the date the letter was mailed. Please use the Script for Obtaining Permission for RAND to Contact Patients
(provided by RAND) when calling patients. Please try to be as persuasive as possible and make it clear to the patient that you are only asking for permission to release their contact information and brief background information to RAND. Giving their permission for the release of this information does not commit them to participating in the study. They can make their final decision about participating in the study when RAND contacts them.

3) Transferring the Patient Screener and Nonresponse Form to RAND

Once you have obtained verbal (either by phone or in person) consent from the patient to release his or her contact and background information to RAND, please complete the Patient Screener and Nonresponse Form (provided by RAND) and fax or mail this form to RAND. Please note that you have to complete a separate form for each patient.

4) Procedures for Patients Who Refuse to be Contacted by RAND

If a patient refuses to give his or her permission to be contacted by RAND, please be sure to ask him or her for permission to release his or her background information to RAND anonymously. This information is very important and will allow RAND to generally describe those patients who chose not to participate in the study. Complete the appropriate sections of the Patient Screener and Nonresponse Form and fax or mail this form to RAND.

5) Procedures for Patients Who Are Deceased

Some patients selected as eligible for the study will be deceased either at the time of selection or may have died between the time they were selected and the time of enrollment. Please complete the appropriate sections of the Patient Screener and Nonresponse Form and mail or fax this to RAND. In addition, please request a copy of the patient’s medical and billing records going back to January 1998 and send it to RAND (provided your institution allows you to do so).

6) Procedures for Patients You Are Unable to Locate

If after you have made a reasonable effort to locate a patient (for example, you have called information and you have looked in the
patient’s medical record to see if they have an alternate address or telephone number) you are still not able to locate a patient, note this on the Patient Enrollment Log. Please complete the appropriate sections of the Patient Screener and Nonresponse Form and mail or fax this to RAND. In addition, please request a copy of the patient’s medical and billing records going back to January 1998 and send it to RAND (provided your institution allows you to do so).

PAYMENT FOR IDENTIFYING AND CONTACTING PATIENTS

Please remember that you will be paid for identifying and recruiting patients for the Cost of Cancer Treatment Study. Each site will receive a minimum of $250 initially and $50 for each patient they identify and attempt to recruit for the study at the end of the recruitment period.